UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2008*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-45* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-5 and 7-45* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 05/16/2008.

Pending claim(s): 1-45. Cancelled claim(s): 6. Amended claim(s): 1-2, 4-5, 7-13, 16-17, 19-27, 30-36, 38-43.

Response to Amendment

As per the rejection of claims 4, 19 under 35 USC 112, second paragraph imposed in the previous Office Action, this rejection is hereby maintained in view of Applicant's failure to properly traverse this rejection.

As per the rejection of claims 1-15, 30-45 under 35 USC 101 imposed in the previous Office Action, this rejection is hereby maintained in view of Applicant's failure to properly traverse this rejection.

It is noted that the official notice taken on page 8-9 in the previous Office Action is taken to be AAPA because Applicant failed to adequately traverse Examiner's assertion.

The amendment filed 05/16/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

amendment shall introduce new matter into the disclosure of the invention. The added

material which is not supported by the original disclosure is as follows:

The newly added portion of the specification reads as follows: "an end user to

pinpoint correlations or ***autocorrelations*** between events, such as example drugs,

dosings, procedures, timing of events etc., and outcomes such as extended length of

stays, mortality, complications infections, etc." (paragraph 0023, emphasis added).

The newly added portion of the specification appears to constitute new matter.

The term "autocorrelation" appears only in claims 4, 19 as originally filed and nowhere

else in the specification as originally filed.

Claims 4, 19 as originally filed reads as follows "a set of rules based on at least

one autocorrelation function executed on the clinically relevant source data".

In particular, "at least one autocorrelation function ***executed on the clinically***

relevant source data" (emphasis added) as previously recited in claims 4, 19 is not the

same as "autocorrelations between ***events, such as example drugs, dosings,***

procedures, timing of events etc., and outcomes such as extended length of

stays, mortality, complications, infections, etc" (emphasis added).

Therefore, Examiner able to find any support for this amendment to the

specification as afforded by the specification as originally filed.

Applicant is requested to clarify the issues discussed above, to specifically point

out support for the newly added limitations in the originally filed specification and claims

to the extent possible, and to cancel any new matter in the reply to this Office Action.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC 112, first paragraph for at least the same rationale as discussed above, and incorporated herein.

Claim Rejections - 35 USC § 112

Claim(s) 4, 19 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As per claim(s) 4, 19, these claims recite "at least one autocorrelation function executed on the transactional clinical records".

Applicant did not point out, nor was Examiner able to find, any support for performing an autocorrelation function on transaction clinical records in the specification as originally filed.

To the extent that the specification as originally filed provides support for autocorrelation, claims 4, 19 previously recited "a set of rules based on at least one autocorrelation function executed on the clinically relevant source data".

No other disclosure was provided with respect to autocorrelation in the specification as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 4, 19 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 4, Examiner cannot ascertain the meaning of "autocorrelation" when read in light of the specification.

For purposes of applying prior art, Examiner interprets this limitation to recite "automated processing".

As per the set of claim(s): 19, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 4, respectively, and incorporated herein.

Additional clarification is requested

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 1-45 is/are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As per claim 1, this claim recites "a computer system" comprising "an input interface", "a set of rules", "a data enhancement layer", and "a storage component".

The recitation "computer" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

As per "an input interface", "a set of rules", and "a data enhancement layer", when read in light of the specification, it appears that all these limitations are purely algorithmic in nature, and are therefore considered to be software *per se*. See MPEP 2106.01(I).

As per "a storage component", Applicant provides no definition for this limitation. Therefore, it could be reasonably interpreted that this limitation encompasses anything capable of storing data, including the human mind and other abstract data storages.

Examiner acknowledge that although claim 1 may envelop statutory embodiments, Examiner submits that claim 1 also envelops nonstatutory subject matter.

All claims dependent thereon, namely claims 2-5, 7-15, fail to remedy the deficiencies, and are therefore rejected for at least the same rationale as applied to parent claim 1 above, and incorporated herein.

As per claim 16, this claim recites a method comprising "generating an enhanced data grouping".

This claim is directed towards nonstatutory subject matter for the following reasons:

First, the method does not require the particulars of another statutory category of invention, i.e. machine, manufacture, or composition of matter. Therefore, it could be reasonably interpreted that any structure capable of performing the recited functionality would be enveloped within the claim scope. In particular, mental steps would fall under the claim scope.

Second, although this claim recites "an enhanced data grouping", this data grouping is not a physical transformation in that object or matter is not transformed from

one state into another. At best, this limitation recites mere data transformation, such transformation does not amount to a physical transformation.

Therefore, claim 16 is directed towards nonstatutory subject matter.

All claims dependent thereon, namely claims 17-29, fail to remedy the deficiencies, and are therefore rejected for at least the same rationale as applied to parent claim 1 above, and incorporated herein.

As per claim 30, this claim recites "a computer system" comprising "input means", rules means", "data enhancement means", and "storing means".

This claim is rejected for substantially the same rationale as applied to claim 1 above, and incorporated herein.

All claims dependent thereon, namely claims 31-37, fail to remedy the deficiencies, and are therefore rejected for at least the same rationale as applied to parent claim 1 above, and incorporated herein.

As per claim 38, this claim recites a "data grouping" comprising "records", "one extended dimension", and "a storing component". When read in light of the specification, this claim appears to recite data structure *per se*. See MPEP 2106.01. See also the rejection of claim 1 above for a discussion of "storing component".

All claims dependent thereon, namely claims 39-42, fail to remedy the

deficiencies, and are therefore rejected for at least the same rationale as applied to

parent claim 1 above, and incorporated herein.

As per claims 43-45, these claims are rejected for at least the same rationale as

applied to the rejection of claims 38-42 above, and incorporated herein.

Additional clarification is requested.

NOTE: The rejection presented hereinbelow if for Applicant's consideration should

Applicant properly traverses the new matter issues discussed above in the response

hereto.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1-5, 7-45 is/are rejected under 35 U.S.C. 102(b) as being anticipated by

Johnson (5664109).

As per claim 1, Johnson teaches a computer system (Figure 1) capable of linking

patient records (reads on "a dimensional enhanced data grouping") (Figure 7),

comprising:

(a) a document repository (reads on "an input interface") capable of receiving a

document containing thereon patient data as provided by a provider (reads on

"transactional clinical records") (Figure 2), wherein the data is provided by a hospital, a

lab, or an insurance company (column 4 line 41-46);

(b) a knowledge base (reads on "a set of rules") (Figure 2 label 218);

(c) software (reads on "a data enhancement layer") capable of communicating

with the document repository and the knowledge base (Figure 2 label 214);

(d) wherein the software is capable of linking (reads on "a dimensional enhanced

data grouping") the document based on the knowledge base (Figure 3);

(e) wherein the link comprises the document and a plurality of links across

metadata of the document (Figure 7);

(f) a database (reads on "a storage component") capable of storing the link

structure (Figure 7).

As per claim 2, Johnson teaches that the link structure is based on:

(a) document metadata (reads on "attributes") (Figure 7 label 706);

(b) document metadata (reads on "variables) (Figure 7 label 706);

(c) conditional linking with a certain degree of certainty (reads on "quantities")

(Figure 6 label 618).

As per claim 3, Johnson teaches that the knowledge base comprises rules as provided by subscribers (reads on "user-defined rules") (column 8 line 8-16).

As per claim 4, Johnson teaches automated processing of documents based on the knowledge base (Figure 2).

As per claim 5, Johnson teaches a plurality of servers capable of processing and storing the link structure (Figure 1 label 116).

As per claim 7, Johnson teaches that the document comprises a patient identifier (reads on "data specific to... a patient"), a hospital identifier (reads on "data specific... to a provider") (Figure 5), a test result (line 9 column 18-19), and current medications (reads on "data specific to... an order") (Figure 5).

As per claim 8, Johnson teaches linking based on a subset of document metadata (reads on "a recombination... based on selected attributes") (Figure 7).

As per claim 9, Johnson teaches a plurality of other link structures (reads on "multiple extended dimensions") (Figure 7 label 714).

As per claims 10-11, Johnson teaches that the system is capable of processing structured data (reads on "hierarchical records") and unfielded data (reads on "multidimensional records") (column 6 line 59-62).

As per claim 12, Johnson teaches storing the link structure in a database (reads on "a transactional data store") (Figure 7).

As per claim 13, Johnson teaches providing an interface capable of accessing the document database (reads on "a datamart") (Figure 8).

As per claim 14, Johnson teaches that the interface is capable of accepting requests and queries for patient records (Figure 8 label 802, 804).

As per claim 15, Johnson teaches formulating a query (It is noted that a query generated by the system for internal use is considered to be "standard query language queries") (Figure 8 label 802, 804).

As per the set of claim(s): 16, 17, 18, 19, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 1, 2, 3, 4, respectively, and incorporated herein.

As per claim 20, Johnson teaches that the following users can submit

documents:

(a) a hospital (column 4 line 45);

(b) a lab (column 4 line 45);

(c) an insurer (column 4 line 45).

Insofar as the remainder of the claim is concerned, the applied art need not teach

these limitations in view of the optional limitations recited therein.

As per claim 21, Johnson teaches that the document comprises a patient

identifier (reads on "data specific to... a patient"), a hospital identifier (reads on "data

specific... to a provider") (Figure 5), a discharge summary (reads on "an event") (Figure

5), a test result (line 9 column 18-19), current medications (reads on "data specific to...

an order") (Figure 5), and a discharge summary (reads on "an administrative or medical

process") (Figure 5).

As per the set of claim(s): 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35,

36, 37, 38, 39, 40, 41, 42, 43, 44, this set of claim is rejected for substantially the same

rationale as applied to the rejection of the set of claim(s): 8, 9, 10, 11, 12, 13, 14, 15, 1,

20, 21, 8, 9, 10, 13, 14, 20, 9, 10, 13, 14, 14/20, 15, respectively, and incorporated

herein.

As per claim 45, Johnson teaches a user interface capable of retrieving patient data over network (Figure 8).

Response to Arguments

Applicant's arguments filed 05/16/2008 have been fully considered but they are not persuasive.

As per newly amended paragraph 0023, on page 12 Applicant argues "As the term was originally in the claims, Applicants submit that the addition to the specification does not constitute new matter".

Examiner submits that claims 4, 19 as originally filed do not provide adequate written description support as to reasonable convey to one of ordinary skill in the art that Applicant had possession of the invention at the time of filing. See above for a discussion of the newly added portion to the specification with respect to the written description support afforded by claims 4, 19 as originally filed.

To properly traverse this objection, Applicant is requested to provide clarifications on how an autocorrelation function executed on clinically relevant source data provides adequate written description support for an autocorrelation between events, such as example drugs, dosings, procedures, timing of events, etc., and outcomes such as extended length of stays, mortality, complications, infections, etc.

Applicant is reminded that the standards for determining compliance of the written description requirement under 35 USC 112, first paragraph does not involve

determining whether the difference between the disclosure as currently amended and the disclosure as originally filed is obvious to one of ordinary skill in the art. Instead, the proper question is whether Applicant had possession of the invention, as currently disclosed, at the time the application was filed. Such possession could be reasonably demonstrated by discussions directed towards inherent or otherwise implicit support provided by the specification as originally filed, and how the current amendment is only making explicit these inherent or implicit facts.

As per claims 4, 19, on page 12 Applicant responds to the rejection under 35 USC 112, second paragraph by amending the specification to include the term "autocorrelation".

Examiner submits that written description support afforded by the specification is not germane to a rejection under 35 USC 112, second paragraph.

Additionally, the newly added portion to the specification does not provide any clarification useful in determining the scope of "autocorrelation".

On page 12 Applicant further argues "one skilled in the art would recognize that autocorrelation is a common method of statistical analysis when time series data is used as supported in paragraph [0023] and Table 4".

Examiner submits that paragraph 0023, either as originally filed or currently amended, provides support for defining autocorrelation as a common method of statistical analysis when time series data is used.

Table 4 also does not provide support for this interpretation.

In fact, paragraph 0023 as originally filed and Table 4 do not even mention autocorrelation.

Paragraph 0023 as currently amended reads as follows: "autocorrelations between **_events, such as example drugs, dosings, procedures, timing of events etc., and outcomes such as extended length of stays, mortality, complications, infections_**, etc" (emphasis added).

Nowhere in paragraph 0023 as currently amended does there exist support for a common method of statistical analysis when time series data is used.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., time series data) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, Applicant has not provided any documentary evidence supporting Applicant's interpretation of "autocorrelation".

As per claim 1, on page 12 Applicant argues "claim 1 submits a practical application of storing generated enhanced data groupings".

Claim 1 recites a "system" comprising software *per se* limitations, as discussed above, and incorporated herein, and "a storage component".

Applicant provides no definition for this limitation. Therefore, it could be reasonably interpreted that this limitation encompasses anything capable of storing data, including the human mind and other abstract data storages.

Therefore, claim 1 is directed towards nonstatutory subject matter by failing to positively recite software components tangibly embodied on computer readable medium.

As per claims 30, 38, 43, Applicant's arguments on page 12-13 merely rehash the arguments previously addressed above, and incorporated herein.

Applicant's arguments with respect to claims 1, 16, 30, 38, 43 on page 13-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Maughan (20030088438) teaches consolidating patient data from a plurality of different sources.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-

270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00

pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
08/03/2008

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626